

2019 年第 5 次第一人體試驗委員會會議記錄

2019 year 5th-A IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2019 年 05 月 14 日（星期二）

二、時間 Time：12:00-13:54

三、地點 Location：福懋大樓 B1 尊榮 B 廳

四、主席 Chairperson：

蘇矢立（院內、醫療、醫師、男性）【IRB180601 利益迴避-研究計畫協同主持人、IRB 151124 利益迴避-PI 為同部門醫師 IRB 180601 Avoiding conflicts of interest- Co-PI, IRB 151124 Avoiding conflicts of interest- Physician of the same department】

Su, Shih-Li (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

■ 陳書毓（院內、醫療、護理、女性）

Chen, Shu-Yu (Affiliation with Institution, Medical Personnel (Scientific member), Nurse, female)

■ 陳恆中（院內、醫療、醫師、男性）

Chen,Heng-Chung (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 顏旭亨（院內、醫療、醫師、男性）

Yen, Hsu-Heng (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 楊小萱（院內、醫療、醫師、女性）

Yang, Shiao-Hsuan (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

■ 江怡蓉（院內、醫療、藥師、女性）

Chiang, Yi-Jung (Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, female)

■ 倪淑鳳（院外、非醫療、社會公正人士、女性）

Shu-Feng, Ni (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)

■ 賴芳足（院外、醫療、公共衛生、女性）

Lai, Fang-Zu (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/Statistics, female)

■ 詹明真（院外、非醫療、法律、女性）【熟稔易受傷害族群-未成年人（7-15 歲），法律專家】

Chan, Melody (Affiliation with Institution (Husband is CCH employee), Nonmedical Personnel (non-Scientific member), Lawyer, female)

- 林志榮（院外、醫療、公衛/統計、男性）
Lin, Jr-Rung Lin (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/ Statistics, male)
- 許耀聰（院外、非醫療、社會人士、男性）
Hsu, YaoChon (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)

	人數	備註
醫療 Medical Personnel	8	醫師(4)、護理(1)、藥師(1)、公共衛生/統計(2)、 doctor (4)、Nurse (1)、Pharmacist (1)、Epidemiology/ Statistics (2)
非醫療 Nonmedical Personnel	3	法律(1)、社工(0)、社會人士(2) Lawyer(1)、Social Worker (0)、Member of society (2)
科學 Scientific member	8	醫師(4)、護理(1)、藥師(1)、公共衛生/統計(2) doctor (4)、Nurse (1)、Pharmacist (1)、Epidemiology/ Statistics (2)
非科學 non-Scientific member	3	法律(1)、社工(0)、社會人士(2) Lawyer(1)、Social Worker (0)、Member of society (2)
男 male	5	院內(3)、院外(2) Affiliation with Institution (3)、non-Affiliation with Institution (2)
女 female	6	院內(3)、院外(3) Affiliation with Institution (4)、non-Affiliation with Institution (2)

備註：♣ 依據「人體研究法」第七條：審查會應置委員五人以上，包含法律專家及其他社會公正人士；研究機構以外人士應達五分之二以上；任一性別不得低於三分之一。審查會開會時，得邀請研究計畫相關領域專家，或研究對象所屬特定群體之代表列席陳述意見。According to Article 7 of the “Human Subjects Research Act:”

“The IRB shall consist of five or more members, including legal expert and other persons of disinterested community members; more than two-fifths shall not be affiliated with the research entity; and no gender shall constitute less than one-third. During IRB meetings, the IRB may invite the attendance of experts familiar with the research field, or representatives of any appropriate group affiliated with the human subjects, to attend and provide comments.

- ♠ 依據「人體研究倫理審查委員會組織及運作管理辦法」第六條：審查會召開一般程序審查會議時，其出席委員應包括機構外之非具生物醫學科學背景委員一人以上。五人以上，不足七人之審查會，應有三分之二以上之委員出席；七人以上之審查會，

應有半數以上之委員出席，始得開會。出席委員均為單一性別時，不得進行會議。According to Article 6 of the “Standards and Operational Guidance for Ethics Review of Human Subject Research.” “Members present at routine review sessions should include at least one with non-biomedical or science background. Two-thirds of entire member should be present for boards with more than 5 and less than 7 members; half of the entire member should be present for boards with more than 7 members before the meeting is commenced. The meeting may not be commenced if the attendee are of the same gender.”

列席人員 Presenting staff：(職稱略 omit title)

- 黃淑萍 (IRB 秘書) Ng Sock Ping (IRB secretary)
- 葉正吉 (IRB 行政人員) Yeh, Cheng Chi (IRB staff)
- 林巧芸 (IRB 行政人員) Lin, Ciao Yun (IRB staff)
- 洪翠霞 (IRB 行政人員) Hung, Tsui-Hsia (IRB staff)
- 李欣儀 (IRB 行政人員) Li, Hsin-Yi (IRB staff)

請 假 Leave：(職稱略 omit title)

- 柯智慧 (院內、非醫療、社工、女性)
Ko, Chih-Hu (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia

五、討論議案：

主題	計畫名稱	決議
編號：190422 【新案】 主持人：蔡易晉	國中小學童暴露空氣汙染導致之呼吸道危害之代謝體研究 Metabolites of Respiratory Hazards of Exposure to Air Pollution in Primary and Secondary School Children	修正後提會
編號：120708 【變更案第 19 次】 主持人：賴冠銘	一項隨機、雙盲、多中心試驗，比較 Denosumab 與 Zoledronic Acid 治療新診斷出多發性骨髓瘤受試者的骨骼疾病 A Randomized, Double-Blind, Multicenter Study of Denosumab Compared With Zoledronic Acid in the Treatment of Bone Disease in Subjects with Newly Diagnosed Multiple Myeloma	修正後複審
編號：130207 【變更案第 13 次】	一項以侵入性麴菌病 (invasive aspergillosis, IA) 的成年和青少年患者為對象，比較經 posaconazole 及	核准

主持人：林炫聿	voriconazole 治療後，所得療效與安全性之第三期隨機臨床試驗 A Phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive Aspergillosis in Adults and Adolescents	
編號：180507 【變更案第 1 次】 主持人：趙美琴	Morquio A 登記試驗 (MARS) Morquio A Registry Study (MARS)	核准
編號：181221 【變更案第 1 次】 主持人：沈銘鏡	一項針對重度 A 型血友病患者出血發作、輸注第八凝血因子(Factor VIII)和病患通報結果的前瞻性非介入性試驗 A Prospective Non-Interventional Study of Bleeding Episodes, Factor VIII Infusions, and Patient-Reported Outcomes in Individuals with Severe Hemophilia A	修正後複審
編號：150308 【期中報告第 4 次】 主持人：陳珊霓	抗血管內皮新生因子治療對其他血管生長因子的影響 The effect of anti-VEGF treatments on other angiogenesis related factors	核准
編號：160207 【期中報告第 3 次】 主持人：蔡易晉	彰化縣國中小學童過敏氣喘疾病與環境相關性之過敏發炎機轉研究 An Environmental Epigenetic Study on Investigating the Immunotoxicological Mechanism of Changhua School Children Asthma	修正後複審
編號：160321 【期中報告第 3 次】 主持人：蔡易晉	彰化縣國中小學童過敏氣喘疾病盛行率調查暨氣喘保健計劃與空氣汙染細懸浮微粒(PM2.5)對學童過敏氣喘疾病發炎機轉研究 Changhua school children asthma screen and health promotion project and Immunotoxic mechanism of air pollution (PM2.5) on pulmonary function and airway inflammation in school asthmatic children.	修正後複審
編號：170310 【期中報告第 2 次】 主持人：林慶雄	針對亞太地區，在穩定的慢性阻塞性肺病(COPD)中以及 COPD 急性惡化(AECOPD)期間，細菌及病毒等潛在病原體的出現 Occurrence of potential bacterial and viral pathogens in stable chronic obstructive pulmonary disease(COPD)and during acute exacerbations of COPD(AECOPD),in Asia Pacific	修正後複審
編號：180601 【期中報告第 1 次】 主持人：杜思德	一項 26 週、隨機分配、雙盲、安慰劑對照、平行分組、多中心的第 3 期試驗與 78 週展延期，評估年滿 55 歲、患有第 2 型糖尿病且血糖控制不當病患使用	修正後複審

	<p>Sotagliflozin 時的療效與骨骼安全性</p> <p>A 26-week Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase 3 Study with a 78-week Extension Period to Evaluate the Efficacy and Bone Safety of Sotagliflozin in Patients 55 years or Older with Type 2 Diabetes Mellitus and Inadequate Glycemic Control</p>	
<p>編號：151124</p> <p>【結案 複審第 2 次】</p> <p>主持人：謝明家</p>	<p>糖尿病與憂鬱之共病影響：臨床與基礎探討</p> <p>Effect of comorbid between depression and Type2 diabetes: investigation from clinical and basic studies</p>	不核准
<p>編號：151124</p> <p>【不遵從事件 回覆 1 次】</p> <p>201903-2</p> <p>主持人：謝明家</p>	<p>糖尿病與憂鬱之共病影響：臨床與基礎探討</p> <p>Effect of comorbid between depression and Type2 diabetes: investigation from clinical and basic studies</p>	存查，同意試驗繼續進行
<p>編號：161207</p> <p>【不遵從事件】</p> <p>201904-8</p> <p>主持人：林炫聿</p>	<p>一項第三期、多中心、隨機分配、雙盲試驗有關 Bortezomib 與 Dexamethasone 合併 Venetoclax 或安慰劑使用於對蛋白西每體抑制劑敏感或未曾接受蛋白西每體抑制劑之復發型或難治型多發性骨髓瘤病患</p> <p>A Phase 3, Multicenter, Randomized, Double Blind Study of Bortezomib and Dexamethasone in Combination with Either Venetoclax or Placebo in Subjects with Relapsed or Refractory Multiple Myeloma Who are Sensitive or Naive to Proteasome Inhibitors</p>	存查，同意試驗繼續進行
<p>編號：180308</p> <p>【實地訪視第 1 次】</p> <p>主持人：陳達人</p>	<p>西達本胺合併諾曼癌素(Aromasin,exemestane)治療荷爾蒙受體陽性晚期乳癌的 III 期臨床試驗</p> <p>A Phase III Trial of Chidamide in Combination with Exemestane in Patients with Hormone Receptor-Positive Advanced Breast Cancer</p>	通過